# Agenda

1. Why CDISC Open Rules Matter
2. The Road to v1.0 – Progress So Far
3. What's Changed (and Why)
4. What's Next on the Roadmap
5. How to Get Involved

# Why CDISC Open Rules Matter

… and why they matter to you …

# CDISC Conformance Rules and Regulatory Requirements

## TODAY

- Various source formats and structures
- Specifications that are not machine-executable
- Variety in interpretations of rule purpose
- Individual implementations to executable code

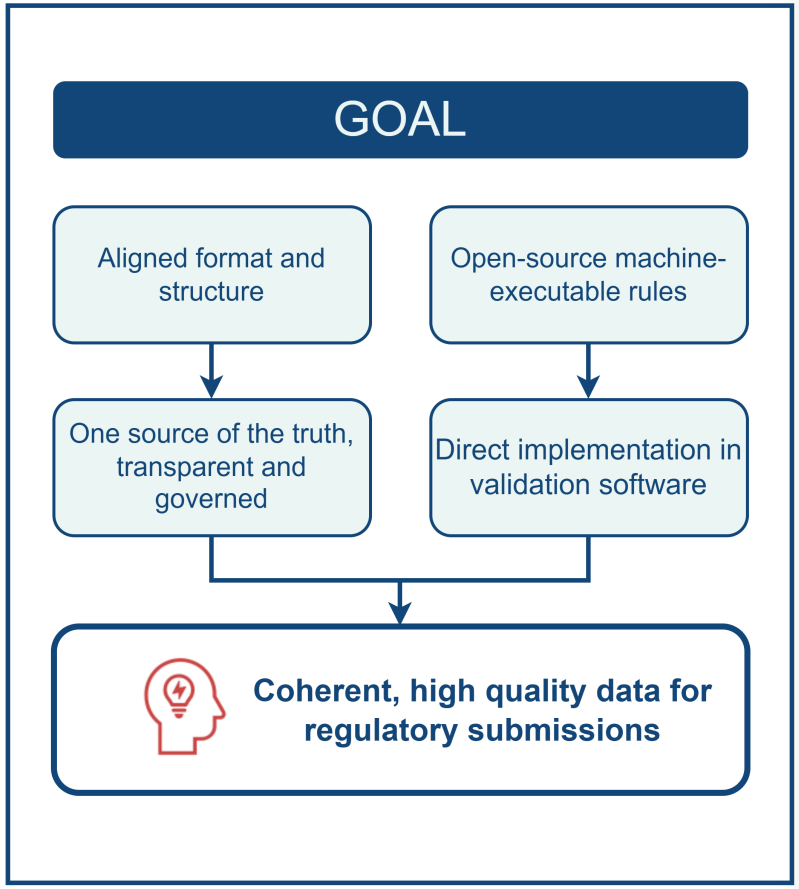
**Lack of consistency in data for regulatory submissions**

## GOAL

- Aligned format and structure
- Open-source machine-executable rules
- One source of the truth, transparent and governed
- Direct implementation in validation software

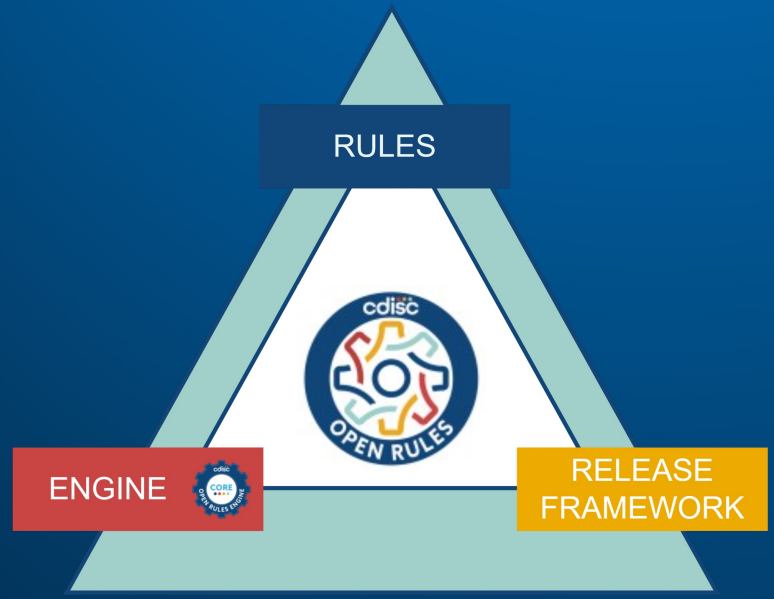
**Coherent, high quality data for regulatory submissions**

# CDISC Conformance Rules and Regulatory Requirements


# Components

- **Rules:** Authored in a simple, low-code format supported by a clear reference structure, enabling easy, transparent, and consistent creation and testing.
- **Engine:** CDISC Open Rules Engine (CORE) processes datasets and executes rules, providing a consistent open-source reference implementation.
- **Release Framework:** Ensures structured review, version control, and coordinated releases to maintain trust and consistency.




*Available in CDISC Open-Source Alliance (COSA), released under MIT license*

# Additional Value for the Industry

- **Reusable Across Lifecycle:** Same conformance rules apply during setup, transfers, analysis, and packaging with automation and reduced manual work.
- **Interoperability:** Vendor-neutral rules provide a shared baseline logic that can be used consistently across tools and organizations.
- **Innovation:** Allows integration of company-specific validation checks and system extensions while remaining aligned with an industry-standard baseline.

# The Road to v1.0 – Progress So Far

# Rule Authoring Status for v1.0

| Standard | # Rules | # Complete | % Complete |
|---|---|---|---|
| SDTMIG v3.2 | 411 | 376 | 91% |
| SDTMIG v3.3 and 3.4 | 505 | 461 | 91% |
| FDA Business Rules (SDTMIG) | 186 | 103 | 55% |
| SENDIG v3.1.1* | 312 | 222 | 71% |
| FDA Business Rules (SENDIG) | 181 | 118 | 65% |
| Unique Rules | 1139 | 884 | 78% |
| TIG v1.0** | 484 | 409 | 85% |
| USDM v3.0 and v4.0** | 260 | 257 | 99% |
| **Unique Rules (Total)** | **1883** | **1550** | **82%** |

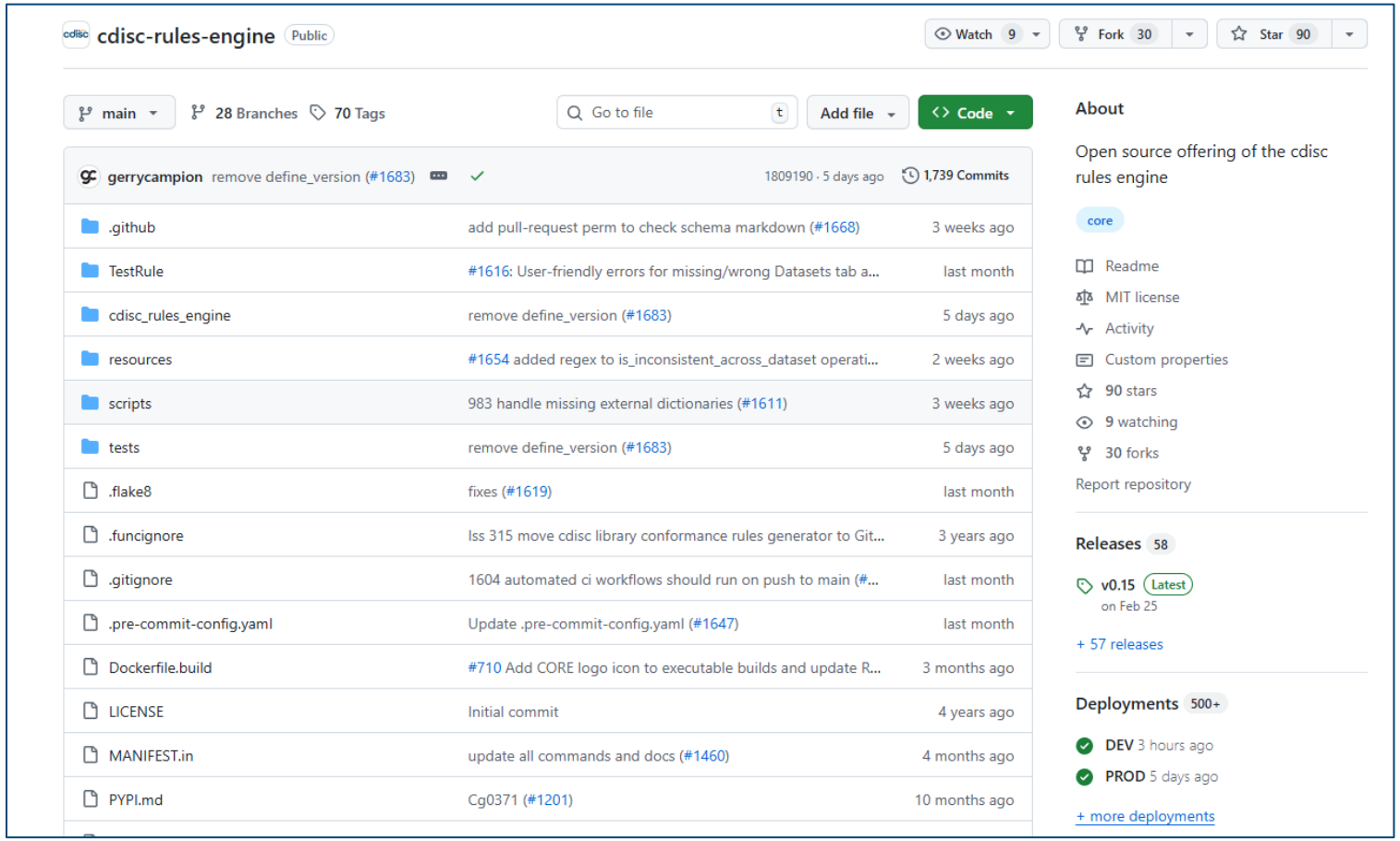
- *SDTMIG v3.2 and SENDIG v3.1.1 rules, not required to be complete for v1.0*
- *TIG v1.0 (partial rule set and only SDTM and SEND related rules) and USDM v3.0 and 4.0 are included in the scope of v1.0, but are separately funded*

# Rule Authoring Status for v1.0

| Standard | # Rules | # Complete | % Complete |
|---|---|---|---|
| SDTMIG v3.2* | 411 | 376 | 91% |
| SDTMIG v3.3 and 3.4 | 505 | 461 | 91% |
| FDA Business Rules (SDTMIG) | 186 | 103 | 55% |
| SENDIG v3.1.1* | 312 | 222 | 71% |
| FDA Business Rules (SENDIG) | 181 | 118 | 65% |
| Unique Rules | 1139 | 884 | 78% |
| TIG v1.0** | 484 | 409 | 85% |
| USDM v3.0 and v4.0** | 260 | 257 | 99% |
| **Unique Rules (Total)** | **1883** | **1550** | **82%** |

- *Pending rules are mostly related to external dictionaries*
- *Started from the FDA Business Rules = very high-level definition of a rule*

# Engine – Current State (v0.15)




- *Development included already 1739 commits*
- *58 releases so far*
- *Solved 1726 tickets*
- *Custom rule schema available*
- *JSONata implemented*
- *…*

# Key Opportunities

| Engine Refactoring | Improved Rule Authoring | Foster Innovation |
| --- | --- | --- |
| Performance | Centralized, trackable workflow | Lower Engineering Dependency |
| Scalability | Built-in automated Testing | Decreased Maintenance |
| Sustainability | Accessible for all volunteers | Author Flexibility |
| | | AI Assisted Rule Authoring |

# Time for Some Reflections…

Lessons learned from building an open, community-driven standard at scale

*We tried our best with what we knew then. Now we know more.*

*Doing it right the first time is great. Doing it better the second time is progress.*

*If no one complained, either it was perfect… or no one was listening.*

# What's Changed (and Why)

# Verisian’s Engine Refactoring

# Verisian’s Engine Refactoring

- Complete internal refactor of the engine architecture to utilise SQL

# Verisian’s Engine Refactoring

- Complete internal refactor of the engine architecture to utilise SQL
- Minimal changes to existing CDISC rule logic, operations, or operators

# Verisian's Engine Refactoring

- Complete internal refactor of the engine architecture to utilise SQL
- Minimal changes to existing CDISC rule logic, operations, or operators
- No additional setup or installation required*

# Verisian's Engine Refactoring

- Complete internal refactor of the engine architecture to utilise SQL
- Minimal changes to existing CDISC rule logic, operations, or operators
- No additional setup or installation required*

*With pgserver the engine runs locally without any performance drop

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| | |
| | |
| | |

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| Failed to run datasets of 1 GB | |
| | |
| | |

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| Failed to run datasets of 1 GB | Successfully ran datasets > 15GB |
| | |
| | |

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| Failed to run datasets of 1 GB | Successfully ran datasets > 15GB |
| Memory-based implementation | |
| | |

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| Failed to run datasets of 1 GB | Successfully ran datasets > 15GB |
| Memory-based implementation | SQL-based implentation with near unlimited scaling |
| | |

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| Failed to run datasets of 1 GB | Successfully ran datasets > 15GB |
| Memory-based implementation | SQL-based implentation with near unlimited scaling |
| No alternative options | |

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| Failed to run datasets of 1 GB | Successfully ran datasets > 15GB |
| Memory-based implementation | SQL-based implentation with near unlimited scaling |
| No alternative options | Embedded alternative with equal capabilities; no additional software installation required |

cdisc®

# Engine Refactoring – Performance Improvements

| Old Engine | Refactored Engine |
| --- | --- |
| Failed to run datasets of 1 GB | Successfully ran datasets > 15GB |
| Memory-based implementation | SQL-based implentation with near unlimited scaling |
| No alternative options | Embedded alternative with equal capabilities; no additional software installation required |

The refactored engine removes dataset size and scalability limitations while improving accuracy and error reporting.

cdisc®

# Rule Authoring

- Full review of the rules was done

# Rule Authoring

- Full review of the rules was done
- Decision was made to
  - Move away from the old rule authoring method
  - Transfer to GitHub as source of truth for all CDISC Open Rules

# Rule Authoring

- Full review of the rules was done
- Decision was made to
  - Move away from the old rule authoring method
  - Transfer to GitHub as source of truth for all CDISC Open Rules
- GitHub keeps track of rule completion status and includes clear version control and review workflows

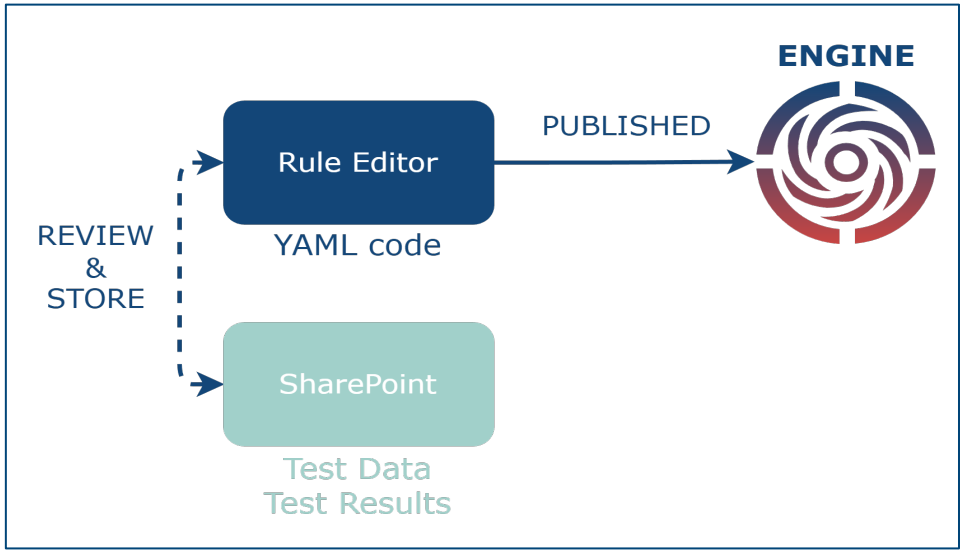
# Rule Authoring

- Full review of the rules was done
- Decision was made to
  - Move away from the old rule authoring method
  - Transfer to GitHub as source of truth for all CDISC Open Rules
- GitHub keeps track of rule completion status and includes clear version control and review workflows
- Built a regression testing model to ensure changes do not affect previously validated rules

cdisc®

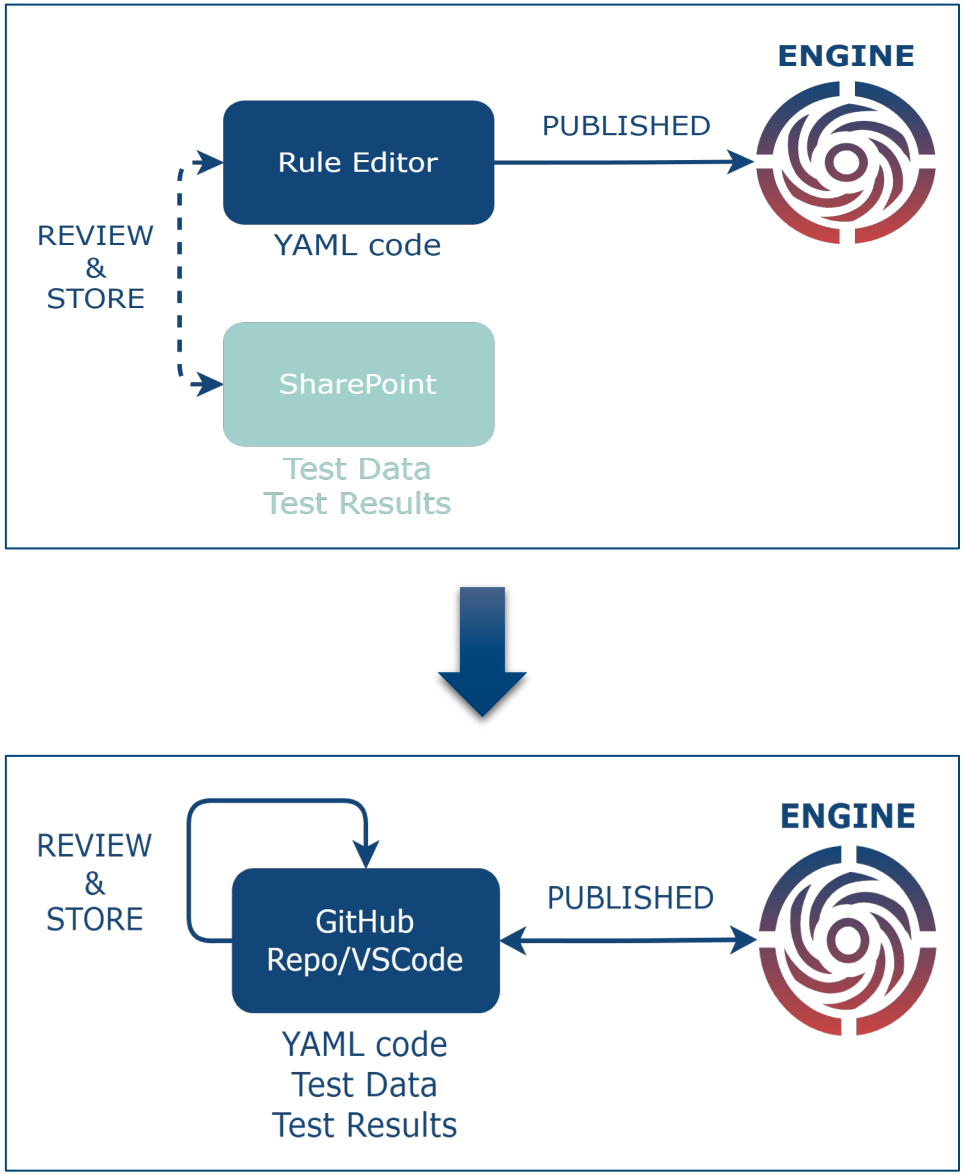
# Rule Authoring

- Full review of the rules was done
- Decision was made to
  - Move away from the old rule authoring method
  - Transfer to GitHub as source of truth for all CDISC Open Rules
- GitHub keeps track of rule completion status and includes clear version control and review workflows
- Built a regression testing model to ensure changes do not affect previously validated rules



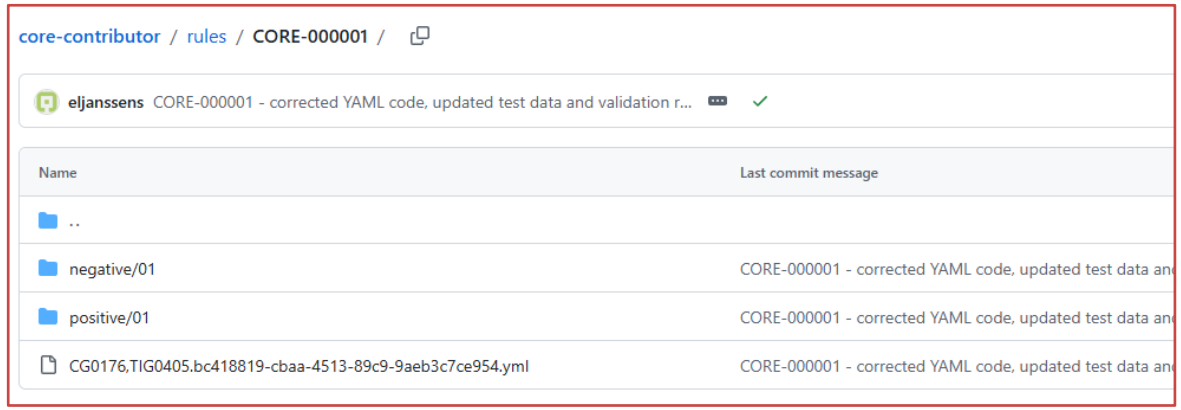
# Rule Authoring

- Full review of the rules was done
- Decision was made to
  - Move away from the old rule authoring method
  - Transfer to GitHub as source of truth for all CDISC Open Rules
- GitHub keeps track of rule completion status and includes clear version control and review workflows
- Built a regression testing model to ensure changes do not affect previously validated rules



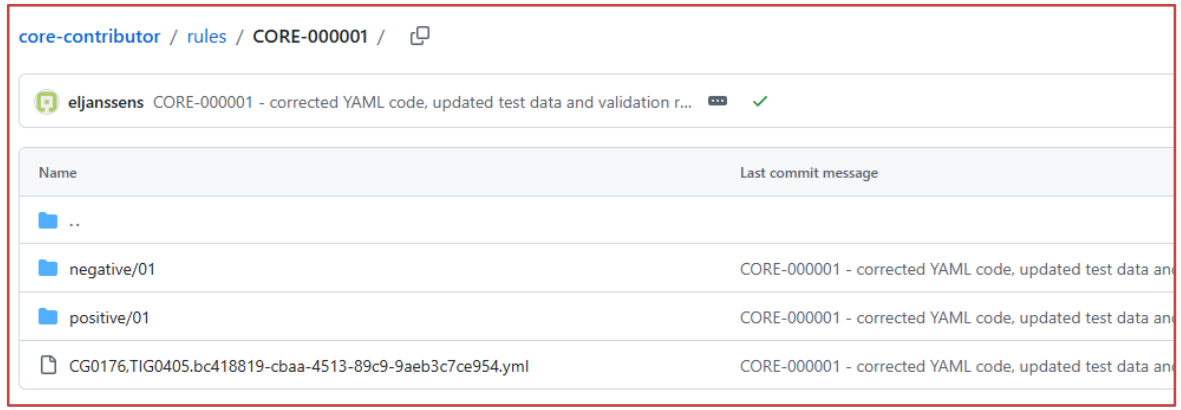
# GitHub Rule Repository – What?

- Stores CDISC Open Rules YAML code, test data and validation results



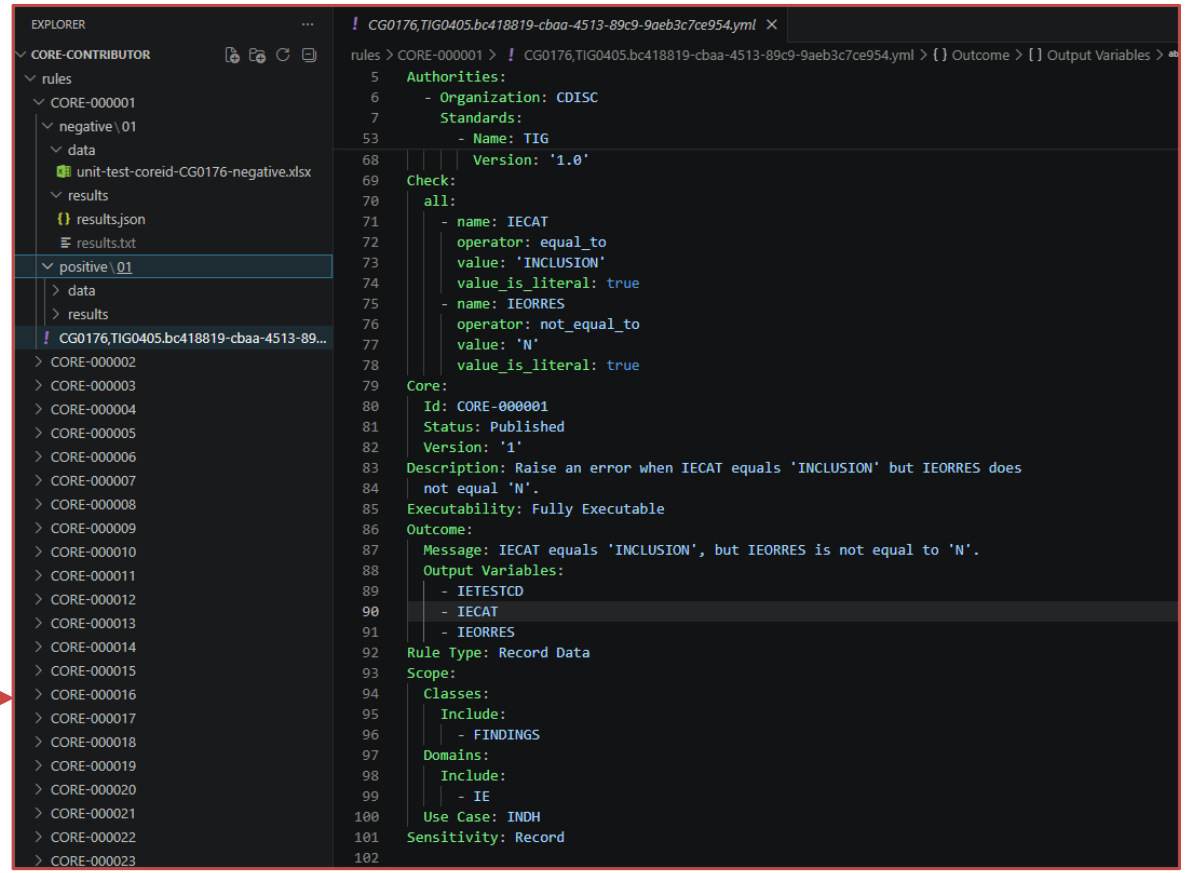
# GitHub Rule Repository – What?

- Stores CDISC Open Rules YAML code, test data and validation results



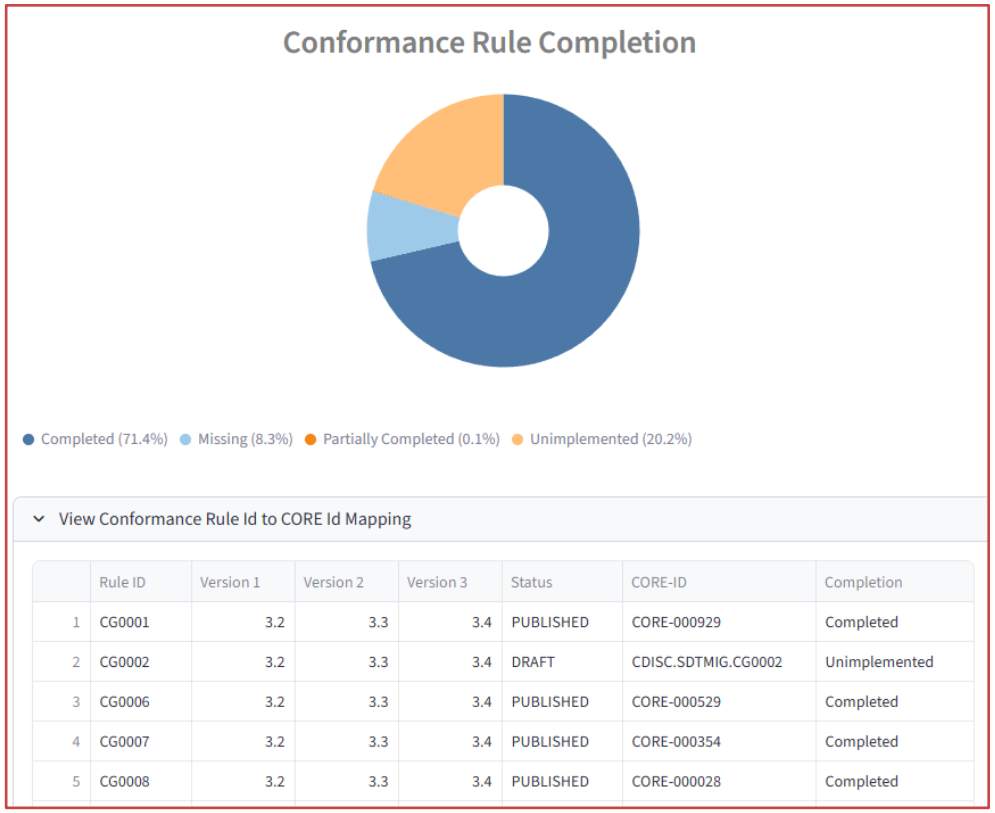

Traceable, transparent and controlled

Writing and automated testing is done in VSCode

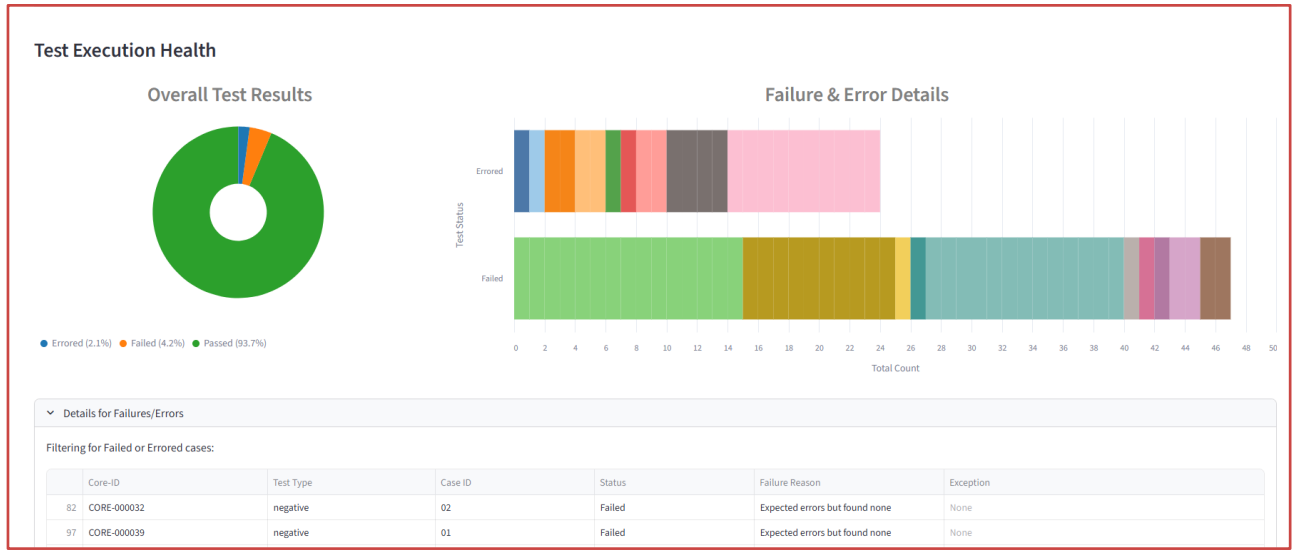


# GitHub Rule Repository – What?

- Streamlit dashboard to track rule completion




| | Rule ID | Version 1 | Version 2 | Version 3 | Status | CORE-ID | Completion |
|---|---|---|---|---|---|---|---|
| 1 | CG0001 | 3.2 | 3.3 | 3.4 | PUBLISHED | CORE-000929 | Completed |
| 2 | CG0002 | 3.2 | 3.3 | 3.4 | DRAFT | CDISC.SDTMIG.CG0002 | Unimplemented |
| 3 | CG0006 | 3.2 | 3.3 | 3.4 | PUBLISHED | CORE-000529 | Completed |
| 4 | CG0007 | 3.2 | 3.3 | 3.4 | PUBLISHED | CORE-000354 | Completed |
| 5 | CG0008 | 3.2 | 3.3 | 3.4 | PUBLISHED | CORE-000028 | Completed |



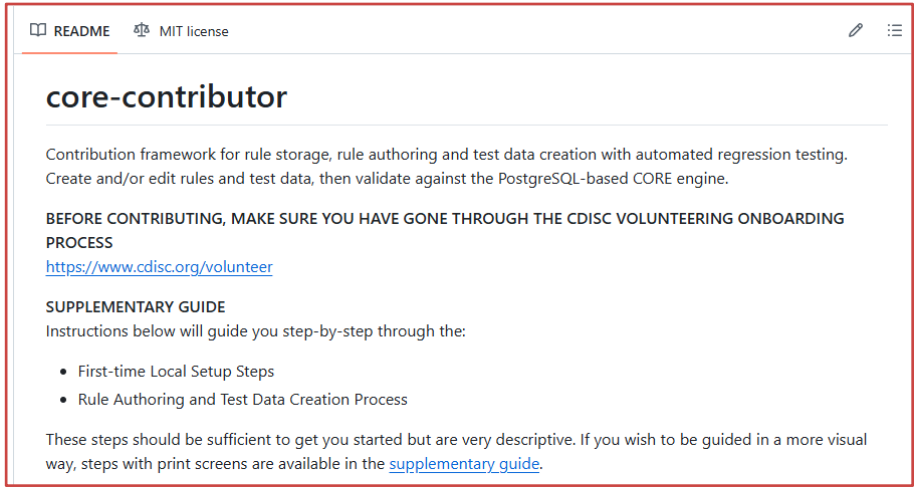

| | Core-ID | Test Type | Case ID | Status | Failure Reason | Exception |
|---|---|---|---|---|---|---|
| 82 | CORE-000032 | negative | 02 | Failed | Expected errors but found none | None |
| 97 | CORE-000039 | negative | 01 | Failed | Expected errors but found none | None |

# GitHub Rule Repository – Contributions Made Easy

- User-friendly setup scripts and a detailed guides
- Training in rule authoring

# GitHub Rule Repository – Contributions Made Easy

- User-friendly setup scripts and a detailed guides
- Training in rule authoring


README MIT license

## core-contributor

Contribution framework for rule storage, rule authoring and test data creation with automated regression testing. Create and/or edit rules and test data, then validate against the PostgreSQL-based CORE engine.

**BEFORE CONTRIBUTING, MAKE SURE YOU HAVE GONE THROUGH THE CDISC VOLUNTEERING ONBOARDING PROCESS**
https://www.cdisc.org/volunteer

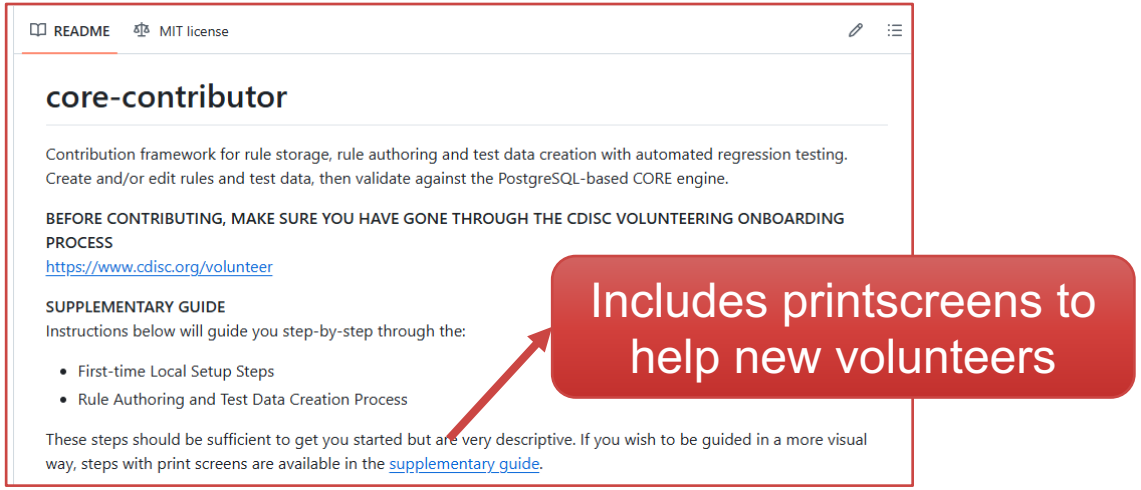
**SUPPLEMENTARY GUIDE**
Instructions below will guide you step-by-step through the:

- First-time Local Setup Steps
- Rule Authoring and Test Data Creation Process

These steps should be sufficient to get you started but are very descriptive. If you wish to be guided in a more visual way, steps with print screens are available in the supplementary guide.

# GitHub Rule Repository – Contributions Made Easy

- User-friendly setup scripts and a detailed guides
- Training in rule authoring



# GitHub Rule Repository – Contributions Made Easy

- User-friendly setup scripts and a detailed guides
- Training in rule authoring

README MIT license

## core-contributor

Contribution framework for rule storage, rule authoring and test data creation with automated regression testing. Create and/or edit rules and test data, then validate against the PostgreSQL-based CORE engine.

**BEFORE CONTRIBUTING, MAKE SURE YOU HAVE GONE THROUGH THE CDISC VOLUNTEERING ONBOARDING PROCESS**
https://www.cdisc.org/volunteer

**SUPPLEMENTARY GUIDE**
Instructions below will guide you step-by-step through the:

- First-time Local Setup Steps
- Rule Authoring and Test Data Creation Process

These steps should be sufficient to get you started but are very descriptive. If you wish to be guided in a more visual way, steps with print screens are available in the supplementary guide.

Includes printscreens to help new volunteers

## First-time Local Setup Steps

***IMPORTANT NOTE***
*You may need your IT support team to install some of the following software for you. In particular, the setup script requires python3.12 to run properly. If you don't have it installed, the script will attempt to install it for you, but this is likely to be blocked by your company settings. If so, you will need to contact IT.*

**Follow steps 1 - 11 carefully.**

1. Create a free GitHub account: https://github.com/signup
2. Install Git, following the instructions here: https://git-scm.com/install
    - When prompted, ensure you check the "**Add to PATH**" option (or select "**Git from the command line and also from 3rd-party software**")
    - Keep all other default settings throughout the installer
    - You DO NOT need to actually run Git as a program, so close any pop-ups that appear after the installation

# GitHub Rule Repository – Contributions Made Easy

- User-friendly setup scripts and a detailed guides
- Training in rule authoring

README MIT license

## core-contributor

Contribution framework for rule storage, rule authoring and test data creation with automated regression testing. Create and/or edit rules and test data, then validate against the PostgreSQL-based CORE engine.

**BEFORE CONTRIBUTING, MAKE SURE YOU HAVE GONE THROUGH THE CDISC VOLUNTEERING ONBOARDING PROCESS**
https://www.cdisc.org/volunteer

**SUPPLEMENTARY GUIDE**
Instructions below will guide you step-by-step through the:

- First-time Local Setup Steps
- Rule Authoring and Test Data Creation Process

These steps should be sufficient to get you started but are very descriptive. If you wish to be guided in a more visual way, steps with print screens are available in the supplementary guide.

Includes printscreens to help new volunteers

## First-time Local Setup Steps

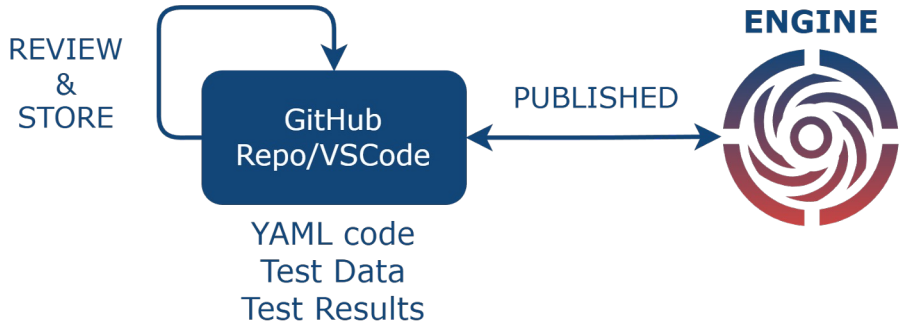
***IMPORTANT NOTE***
*You may need your IT support team to install some of the following software for you. In particular, the setup script requires python3.12 to run properly. If you don't have it installed, the script will attempt to install it for you, but this is likely to be blocked by your company settings. If so, you will need to contact IT.*

**Follow steps 1 - 11 carefully.**

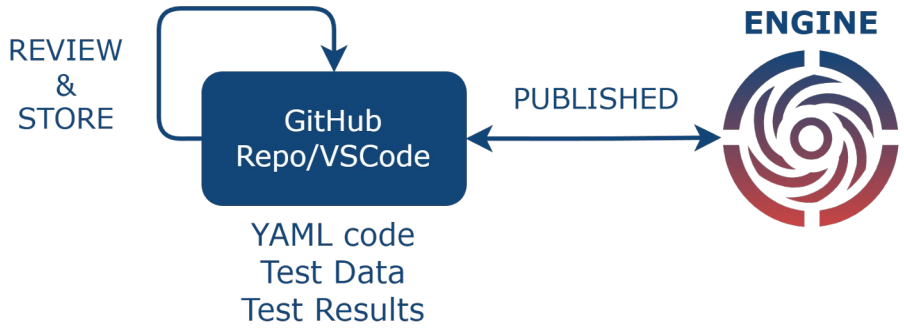
1. Create a free GitHub account: https://github.com/signup
2. Install Git, following the instructions here: https://git-scm.com/install
   - When prompted, ensure you check the "**Add to PATH**" option (or select "**Git from the command line and also from 3rd-party software**")
   - Keep all other default settings throughout the installer
   - You DO NOT need to actually run Git as a program, so close any pop-ups that appear after the installation

Easily write Rules and perform Unit Testing within the repository

# Improved Rule Authoring Process



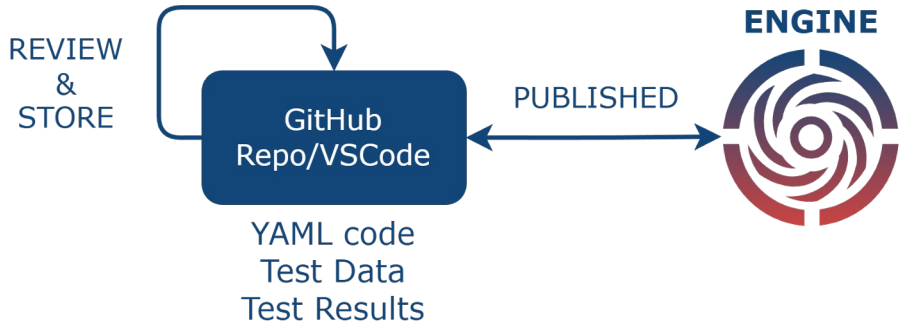
# Improved Rule Authoring Process




## Centralized and Trackable Workflow

- Git-based rule repository for storing, versioning, and tracking
- Streamlit dashboard for quick analysis and progress visibility

# Improved Rule Authoring Process



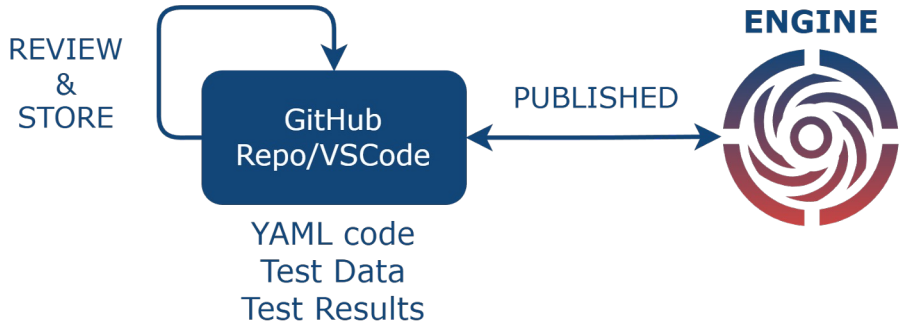

## Centralized and Trackable Workflow

- Git-based rule repository for storing, versioning, and tracking
- Streamlit dashboard for quick analysis and progress visibility

## Easy and Guided Contribution

- Simple setup scripts and clear contributor guide
- Accessible to all skill levels
- Structured review process

# Improved Rule Authoring Process




## Centralized and Trackable Workflow

- Git-based rule repository for storing, versioning, and tracking
- Streamlit dashboard for quick analysis and progress visibility

## Easy and Guided Contribution

- Simple setup scripts and clear contributor guide
- Accessible to all skill levels
- Structured review process

## Integrated Training and Testing

- Built-in training materials
- Automated testing within the repository

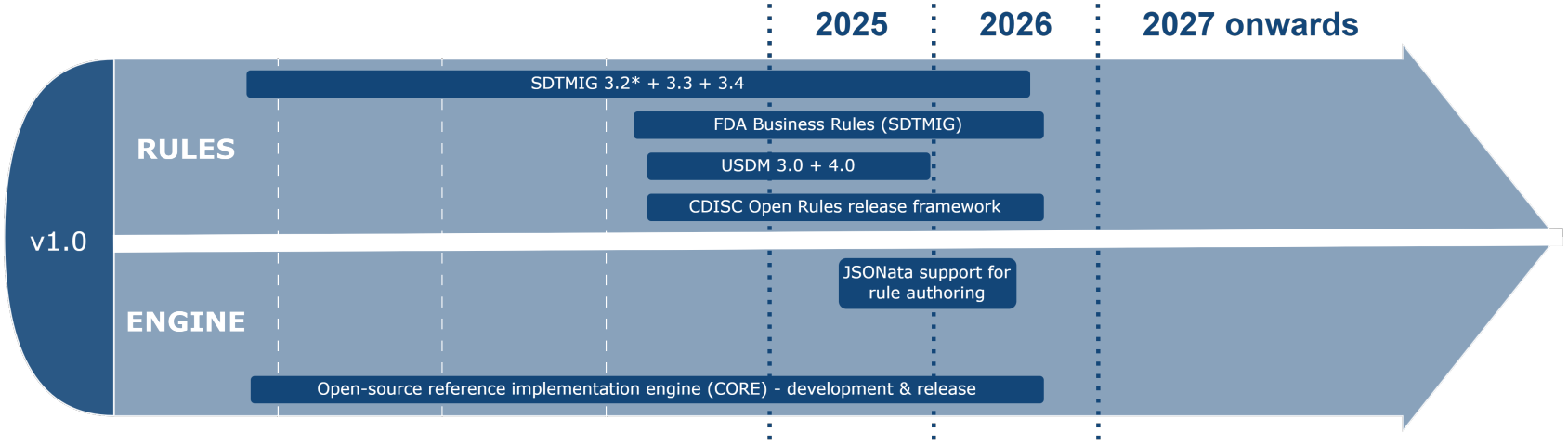
cdisc®

# What's Next on the Roadmap

# Roadmap

***Note** that Roadmap timelines are estimates, depend on volunteer-driven progress.*

** SDTMIG 3.2 will be created but are not required to be complete for v1.0*




Transferring CDISC Open Rules for SDTMIG and FDA Business Rules (SDTMIG) to GitHub Repository

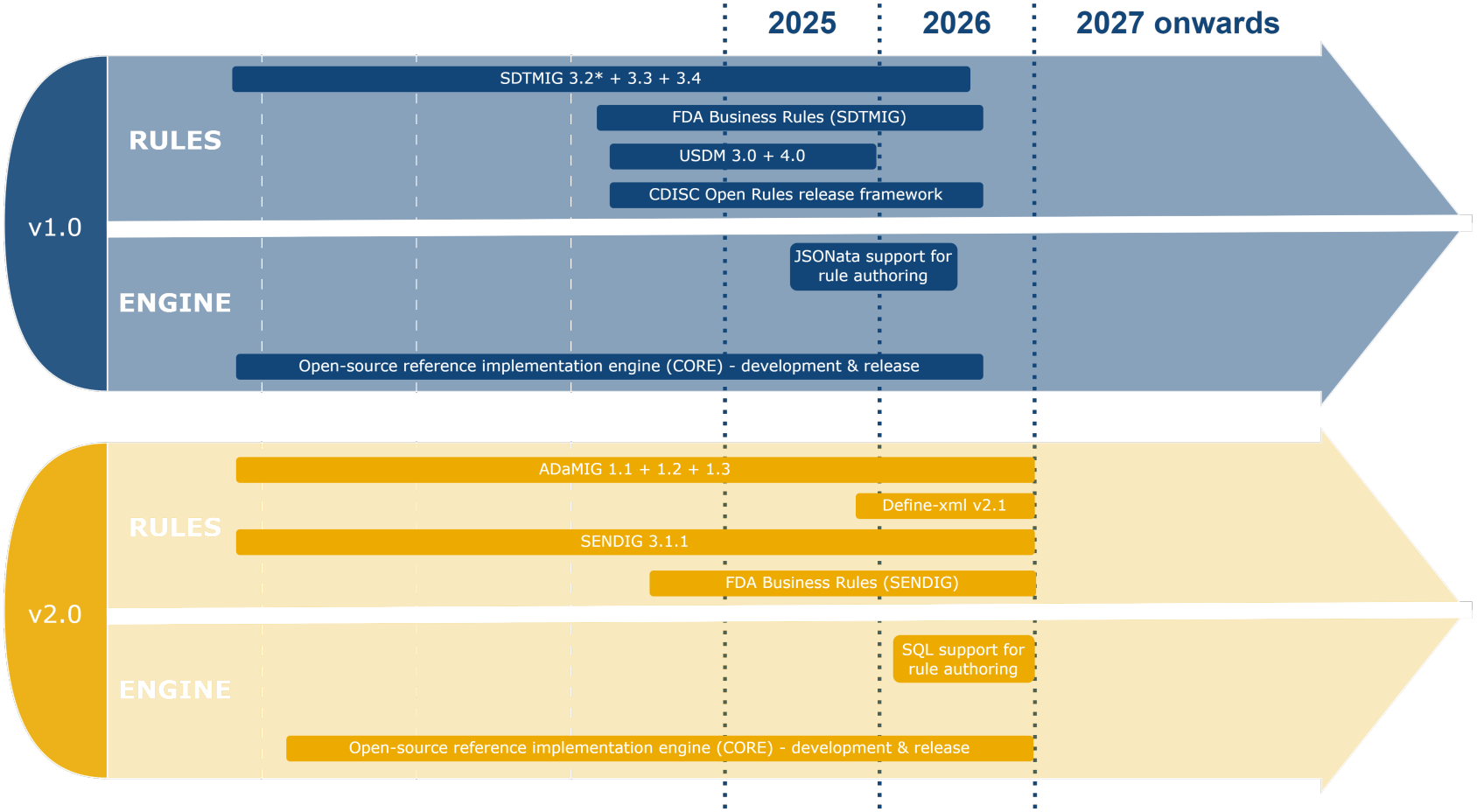
Further building the GitHub Repository for CDISC Open Rules for other standards

Roll out a release framework for the rules and the engine

# Roadmap

***Note** that Roadmap timelines are estimates, depend on volunteer-driven progress.*

** SDTMIG 3.2 will be created but are not required to be complete for v1.0*



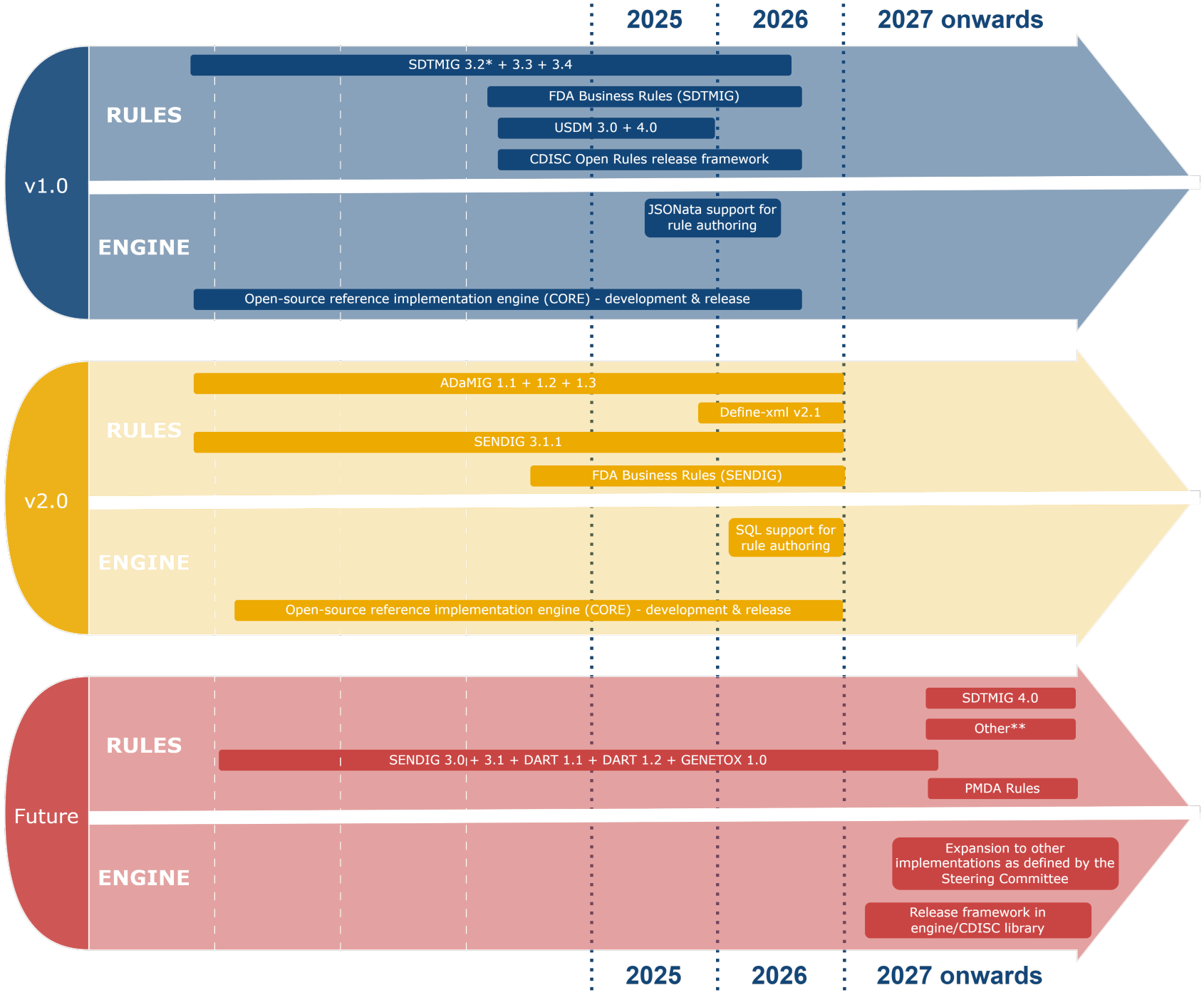

ADaM and define-xml experts are very much welcome for the next phase

# Roadmap

***Note** that Roadmap timelines are estimates, depend on volunteer-driven progress.*

** SDTMIG 3.2 will be created but are not required to be complete for v1.0*

*** All remaining standards not regulatory required, updates to existing conformance rules, AI-driven rule authoring,...*



# How to Get Involved

# Volunteering

The success and completion of CDISC Open Rules is community driven

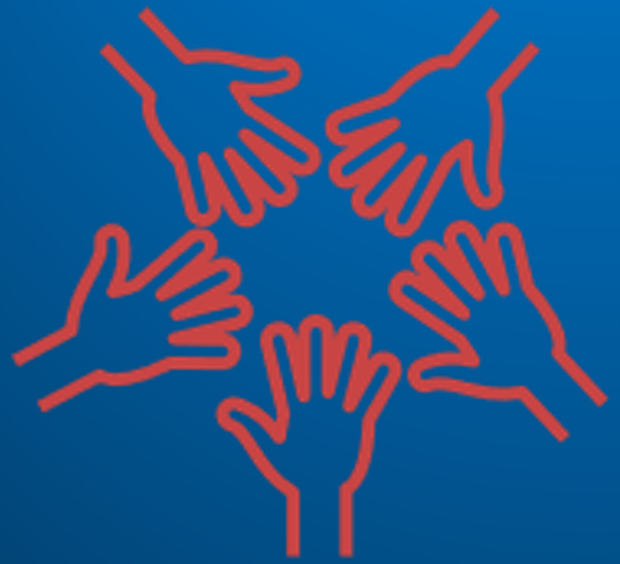
**Rules need to be transferred to the GitHub Rule Repository, including a validation run**


*We currently have 13 contributors in our GitHub Rule Repository, successfully creating and validating CDISC Open Rules*

# Volunteering

The success and completion of CDISC Open Rules is community driven

## Join us in shaping the future of CDISC Open Rules



*Sign up as a volunteer*